

U.S. Patent Application No. 10/774,076
Attorney Docket No. 161 US UT01

REMARKS

Claims 1-10, 13-16, and 18-45 are pending in the above-identified application. Claims 27, 29-31, and 33-45 were withdrawn from further consideration by the Examiner as being drawn to a nonelected invention, therefore only claims 1-10, 13-16, 18-26, 28, and 32 were examined. The claims are rejected or objected to for various reasons as described below. Claims 1-3, 8-10, 18, 22, 23, and 25 are amended herein for clarity and claims 16, 19, and 26 are cancelled. No new matter is added to the claims as the claims are amended for clarity, e.g., as requested by the Examiner or to incorporate the language of dependent claims into the independent claims. Applicants respectfully request that the amendments to the claims be entered.

The specification is also amended herein. Amendments are made to the specification as requested by the Examiner and to correct typographical errors. No new matter is added to the specification and Applicants respectfully request that the amendments be entered.

In addition, Applicants note that references 7-25 and 30 from Applicant's IDS filed 11/24/04 have not been considered by the Examiner and are providing them under separate cover for consideration by the Examiner.

Objections to the Specification

The specification was objected to for lack of trademark symbols in certain instances. The specification is amended herein to include trademarks symbols, and generic terminology as requested by the Examiner. Additional typographical errors in the specification are also corrected in the amendments provided herein. No new matter is added by these amendments. Applicants respectfully request that the objection to the specification be withdrawn.

Objections to the Claims

Claim 1 was objected to due to informalities regarding the use of abbreviations and a typographical error. Claim 1 is amended herein to correct these informalities as requested.

In addition, Claim 15 was objected to as depending upon a rejected claim. The claim from which claim 15 depends is amended herein and Applicant believes that all claims, as

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provided herein, are in condition for allowance and respectfully request that the objection be withdrawn.

The Claims Are Not Indefinite

Claims 3, 16, and 26 were rejected under 35 U.S.C. § 112, second paragraph for alleged indefiniteness due to the use of terms such as "PAR34" and "PAR80," instead of sequence identification numbers. Claim 3 is amended herein to refer to sequence identification numbers and Claims 16 and 26 are cancelled. Applicants therefore request that the rejection be withdrawn.

The Claims Are Enabled by the Specification

Claims 1-10, 13-14, 16, 18-26, 28, and 32 are rejected under 35 U.S.C. § 112, first paragraph for an alleged lack of enablement. The Examiner states:

"the specification, while being enabling for a chimeric or human antibody that competitively inhibits binding of an amphiregulin (AR) polypeptide to an anti-AR antibody that consists of SEQ ID NOs: 2, 3, 4, 5, 12, or 14 to treat psoriasis, does not reasonably provide enablement for antibody fragments that competitively inhibit binding of an AR, at least 80% identical or at least 98% identical or polymeric, allelic variants, mutant, interspecies homolog or conservatively modified variant sequence to SEQ ID NO:1 to anti-AR antibody or any antibody fragments, or any chimeric or human antibody consisting of at least 60% identical to the SEQ ID NO: 2, 3, 4, 5, 12, or 14 to treat cancer."

The focus of the rejection seems to be an alleged lack of enablement regarding antibodies that bind to polypeptide sequences that are 80% and 60% identical to the amphiregulin sequence of the invention. Applicants herein amend the claims to clarify that the antibodies of the invention bind to the amphiregulin sequence of SEQ ID NO: 1, which, as the Examiner acknowledges, is enabled by the specification. Applicants believe that the claims as amended are enabled by the specification and respectfully request that the rejection be withdrawn.

The Claims Are Supported by the Written Description

Claims 1-10, 13-14, 16, 18-26, 28, and 32 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter that is not described in the specification, e.g., antibodies that bind to a polypeptide that is 80% identical to SEQ ID NO: 1. Applicants

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herein amend the claims to clearly state that the antibodies of the invention bind to SEQ ID NO:

1. The specification clearly describes such antibodies, as acknowledged by the Examiner.

Applicants therefore, respectfully request that the rejection be withdrawn.

The Claims Are Not Anticipated by Sato

Claim 10 is rejected under 35 U.S.C. § 102(e) for alleged anticipation by Sato (US Patent 6,677,436). The Examiner states that Sato teaches an antibody that is 80% identical to the antibodies of the invention. Applicants amend herein to increase the sequence identity requirement to 95 % identity. The claims, as amended, are not anticipated by Sato and Applicants request that the rejection be withdrawn.

The Claims Are Not Obvious Over Shoyab in view of Kaplan

Claims 18-26 are rejected under 35 U.S.C. § 103(a) for alleged obviousness. The examiner alleges that the claims are obvious under Shoyab (US Patent 5,830,995) in view of Kaplan (US Patent 4,668,629). The claims are amended herein for clarity and as described below the claims are not obvious over Shoyab in view of Kaplan.

Three requirements must be met for a prima facie case of obviousness. First, the prior art reference must teach all of the limitations of the claims. M.P.E.P. § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. Furthermore, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on Applicant's Disclosure. M.P.E.P. § 2142.

The claims, as amended, clarify that the antibodies of the invention bind to the same epitope of amphiregulin as antibodies corresponding to SEQ ID NOs: 2, 3, 4, 5, 12 and 14. Shoyab does not teach antibodies that bind to the same epitope as antibodies of the invention, therefore the cited references do not teach every element of the claimed invention. Furthermore, no motivation to combine or expectation of success is found in the prior art. The claims are not obvious and Applicants respectfully request that the rejection be withdrawn.

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CONCLUSION

Amendments have been made to overcome all objections due to informalities and rejections due to 35 U.S.C. § 112, first and second paragraphs. Applicants therefore request that the objections and rejections under 35 U.S.C. § 112 be withdrawn. In addition, the references cited as prior art under 35 U.S.C. §§ 102 (e) and 103 (a) do not teach every element of the claimed invention. Therefore the invention is not anticipated by or obvious over the references. Applicants therefore respectfully request that the rejections for alleged obviousness and anticipation be withdrawn. In view of the foregoing, Applicants believe that the application is in good and proper condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (510) 284-8868.

Respectfully submitted,

Dated: _____

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